JUL 0 6 2000

12. 510(k) Summary

K001596

Trade Name: LifeRx
Common Name: Medical Image Processing System
Classification Panel: Radiology
Date of summary: April 27, 2000

Submitter:

BowdenGS Technologies, LLC
54 Rock Church Dr.
O'Fallon, MO 63366
Phone: (636)978-8846

Contact Person: Jeffrey James Bowden

Predicate Device: Cheshire(K952778) from Parexel/Perceptive Systems, Inc.

Description of the Device: This image processing software package is intended for use with medical images. It has many capabilities that are common among image processing software packages. Besides the standard features of viewing medical images, window level controls, multiple palettes, and basic ROI capabilities, this software has a number of features that make it unique in evaluating images. Such as, viewing and processing information associated with the header of medical images, as well as the ability to mask, separate and merge image sets. Medical image data is obtained from imaging file formats that are either published, or are licensed from medical device manufacturers.

Many of the tools supplied in LifeRx are useful for reformatting data for other purposes. An example of this would be the process of eliminating patient information in image headers, extracting specific images from an image set, and masking specific portions of the images so that patient confidentiality is preserved when sending images to colleges over the Internet or via Sneakernet (i.e. Floppy disk or any media that requires the user to actually move from one computer to the other and extract the data from a piece of media.)

Intended use: To aid medical professionals in viewing, analyzing, and processing image data acquired through third party medical imaging devices that have been proven and given clearance for use by the FDA. This is achieved by reading image data files into the software from formats obtained from published material or are licensed from medical device manufacturers.

Technological Characteristics: This and the predicate device are designed to operate with the same intended use, under the same conditions, with the same data, and with similar tools and abilities. From this it is concluded that they are substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 06 2000

Jeffrey James Bowden
Partner
BowdenGS Technologies, LLC
54 Rock Church Drive
O'Fallon, MO 63366

Re: K001596
LifeRx™ (Medical Image Processing System)
Dated: May 16, 2000
Received: May 23, 2000
Regulatory Class: II
21 CFR 892.2050/Procode: 90 LLZ

Dear Mr. Bowden:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

Ver/ 3 - 4/24/96

Applicant: BowdenGS Technologies, LLC

510(k) Number (if known): K001596

Device Name: LifeRx

Indications For Use:

Indications

LifeRx™ is indicated for use by medical professionals to aid in viewing, analyzing, and processing image data acquired through third party medical imaging devices that have been proven and given clearance for use by the FDA. This is achieved by reading the image data files into the ***LifeRx™*** software using formats obtained from published material or licensed from medical device manufacturers.

Clinical Settings

LifeRx™ is intended to be used in the clinical settings encompassed by pharmaceutical research and clinical diagnostics. ***LifeRx™*** will be used by medical professionals to view medical images at hospitals and institutions. It will also be used by medical professionals to evaluate the images required in clinical trials by the pharmaceutical industry.

Target Population

The target population of ***LifeRx™*** is medical professionals associated with clinical diagnostics and pharmaceutical research.

Anatomical Sites

Since the viewing, analyzing, and processing of images by ***LifeRx™*** can be applied to any image set acquired via approved hardware it is independent of the anatomical regions that have been imaged.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K001596

Prescription Use ✓
(Per 21 CFR 801.109)